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10/735,526	12/11/2003	Jeffrey S. Bland	062114-0077	3771

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EXAMINER

NOAKES, SUZANNE MARIE

ART UNIT PAPER NUMBER

1656

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/735,526

Applicant(s)

BLAND ET AL.

Examiner

Suzanne M. Noakes, Ph.D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 and 25-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

DETAILED ACTION

1. The Examiner and Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Suzanne Noakes in Art Unit 1656.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-8 and 15-24 in the reply filed on 07 September 2006 is acknowledged. The traversal is on the ground(s) that Group I, drawn to a method of balancing a bodily process that utilizes S-adenosylmethionine (SAM) can also be used to treat the diseases as stated in Group II, which is drawn to methods of treating or preventing disease conditions involving bodily processes that utilize SAM. This is not found persuasive because in certain circumstances managing and treating/preventing are very different things and a search for each of the distinct inventions of Groups I-II is not co-extensive. This is particularly relevant to the literature search because the method of Group I addresses managing a bodily process that may or may not entail treating or preventing a disease as stated in Group II such as cancers and in particular "hot flushes". Thus, the search strategy for invention claimed in Group I method will be entirely different than the search strategy in Group II method. Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to

examine all of the inventive Groups in one application. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 112.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/265,908, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The provisional application discloses a medical food that might be beneficial in managing symptoms that relate to the female hormone cycle only, specifically, treatment of premenstrual syndrome (PMS). There is no disclosure or contemplation of treating said PMS with a medical food that must contain an isoflavone, and isoflavone synergist and a methylation compound. Rather, the disclosure teaches a medical food which might contain any or

Art Unit: 1656

all of the following: flavonoids (e.g. isoflavones), carotenoids, amino acids, trace elements, minerals, water soluble vitamins, fat soluble vitamins, carbohydrates, lipids, proteins, botanicals, fiber and other ingredients. Thus, the claims do not find support in just isoflavones and there is no disclosure of any sort of isoflavone synergist, or why one would selectively limit any sort of composition to possess minimally just an isoflavone, isoflavone synergist and a methylation support compound. Thus, in the absence of this support and in because the provisional application is limited specifically to methods of helping to maintain a healthy balance of female hormones rather, whereas the scope of the instant application is drawn to treating or managing any bodily process that involves the SAM pathway, the provisional application does not provide adequate 35 U.S.C. 112 written description or enablement to support the instant application. Thus, for prior art purposes, the priority date afforded the instant application is that of the CIP application, 10/056,858 filed 23 January 2002.

Claim Objections

4. Claims 23 and 24 are objected to because of the following informalities: The claim is grammatically incomplete because 'wherein the carotenoid is at least compound....' should have the article 'a' in front of compound . Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting - Statutory

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 1-8 and 15-24 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8 and 15-24 of copending Application No. 11/249,849 (US 2006/0034954). This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Double Patenting – Non-Statutory

8. Claims 1-8 and 15-24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-82 of

Art Unit: 1656

copending Application No. 11/100,761. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant method of managing a bodily process by administering a composition *comprising* a mixture of an isoflavone, an isoflavone synergist and a methylation support compound wherein dependent claim 2 specifically states that the bodily process is a hormone imbalance, would be obvious over a medical food disclosed claimed in 11/100,761 comprising a mixture of macronutrients (e.g. proteins, carbohydrates and lipids) and micronutrients which comprise an isoflavone, an isoflavone synergist and a methylation support compound for estrogen metabolites, wherein said food mixture is used to treat a hormone imbalance.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1656

10. Claims 1-8, 15 and 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Bagchi et al. (US 2001/0039296).

Bagchi et al. teach a method for preventing and or reducing the symptoms of menopause in women, wherein menopause is identified by a hormone imbalance wherein said imbalance is caused by a reduction of the hormone estrogen (see p. 1, paragraph 002), by administering a composition comprising an isoflavone, and isoflavone synergist and a methylating support compound possessing soy isoflavone, trans-resveratrol (e.g. isoflavone synergist) and folic acid (methylating support compound). Specifically it is stated on p. 2, paragraph 12 (and repeated in claims 1-8):

*"A preferred embodiment of the invention comprises administering a composition comprising 1-10 mg Protokin extract (as a source of 0.5 to 5 mg **trans-resveratrol**), 5-30 mg **soy isoflavones**, 25-150 mg **calcium lactate**, 40-400 IU **vitamin D-3**, 12.5-75 mg **zinc-L-monomethionine**, 3-10 .mu.g **vitamin B-12**, and 5-20 .mu.g **folic acid**. This particular composition comprises what are considered effective amounts of the various compounds, *and it provides for particular synergistic effects for a wide range of symptoms associated with menopause and other female health remedies, such as the side effects associated with estrogen treatment therapies.*"*

Thus the combination disclosed meets not only claims 1-8 inherently, but also, trans-resveratrol meets claim 17 as an isoflavone synergist; soy isoflavones meets claim 15, folic acid meets claim 18 as a methylating support compound (claim 18) and the combination thereof meets claims 1-8. Furthermore, calcium lactate meets claims 19 and 21 as a mineral source; vitamin D-3 meets claims 19 and 20 as a vitamin source; zinc-L-monomethionine meets claim 19 and 21 as a mineral source; vitamin B-12 meets claim 19 as a vitamin source. Although, the disclosure is silent on the particular pathway which said composition influences (e.g. the SAM pathway), it is

Art Unit: 1656

deemed that intrinsically and inherently that this composition will necessarily work on the SAM pathway and that one skilled in the art would recognize this as such.

11. Claims 1-8, 15, 17-20 and 22-24 rejected under 35 U.S.C. 102(b) as being anticipated by Gaynor et al. (US 5,904,924).

Gaynor et al. teach a food supplement wherein their invention states:

"The present invention is directed to a composition of natural and herbal products which may be compounded in dry form into a mixture which is readily soluble in a fluid for ingestion by humans. Specifically, the new mixture, when digested, has provided users of the same with an energy boost and associated feelings of well being when the mixture is taken as part of a regular regimen to supplement normal nutritional intakes *and to supplement any therapeutic processes to which the users may be subject.*"

The food supplement, while containing many other ingredients, comprises the following (see claim 1):

<u>Ingredient</u>	<u>Claims anticipated</u>	<u>Instant App. Equivalent</u>
Rosemary	(claims 1 and 17)	Isoflavone synergist
Curcumin	(claims 1 and 17)	Isoflavone synergist
Soy isoflavone	(claims 1 and 15)	Isoflavone
Folic acid	(claims 1 and 18)	Methylation Support Com.
Choline bitrtrate	(claims 1 and 18)	Methylation Support Com.
Lycopene	(claims 1, 19 and 23)	Carotenoid
N-acetyl-L-cysteine	(claims 1, 19 and 22)	Fortifying Amino Acid
Thiamine HCl [Vitamin B-1]	(claims 1, 19 and 20)	Vitamin
Biotin	(claims 1, 19 and 20)	Vitamin
Riboflavin [Vitamin B-2]	(claims 1 and 19)	Vitamin
Pyridoxine HCl [Vitamin B-6]	(claims 1 and 19)	Vitamin
Vitamin B-12	(claims 1 and 19)	Vitamin
Blue Green Algae/Quercetin	(claims 1, 19 and 24)	Flavonoid

It should be noted that while the table does not expressly state 'quercetin', the blue-green algae source is used expressly to obtain/include quercetin in the composition. See column 1, lines 61-64.

It is determined that administration of said food supplement as taught by Gaynor et al. will inherently and necessarily result in the management of bodily processes which utilize S-adenosylmethionine (SAM) in a pathway. While Gaynor et al. are silent on this aspect and the pathway(s) utilized by the composition, administering said composition will inherently work on processes where there is an estrogen hormone imbalance and the pathways and enzymes are those stated in claims 2-8. Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility**. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. (3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing. In the instant case, administration of the composition as taught by Gaynor et al., which possesses an isoflavone, and isoflavone synergist and a methylation support compound will thus inherently treat a bodily process of estrogen hormone imbalance in a pathway catalyzed

Art Unit: 1656

by catechol O-methyltransferase (COMT) or S-adenosyl-L-methionine:delta-24[25]sterol methyltransferase, and wherein the pathway methylation of a compound is one of several biomolecules such as hormones or DNA. Furthermore, it would be recognized by a skilled artisan that the combination of rosemary and curcumin, isoflavone synergists; soy isoflavone, Isoflavone; and the methylation support compounds folic acid and cholin bitrtrate will necessarily always be capable of managing said bodily processes.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-8 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagchi et al. (US 2001/0039296) in view of Mazur et al. (Nutritional Biochemistry, 1998, 9:193-200).

Bagchi et al. teach a method for preventing and or reducing the symptoms of menopause in women as by administering a composition comprising soy isoflavone, an isoflavone synergist and a methylating compound as described in Section 8 above.

Bagchi et al. further teach:

"Naturally occurring phytoestrogens are useful compounds in the present invention. These compounds can mimic the effects of estrogen in alleviating the

Art Unit: 1656

negative health effects of menopause, without increased cancer risk.” (see paragraph 0008).

Bagchi et al. however do not teach using isoflavones derived from kudzu rather than soy in the composition used to manage a bodily process (menopause) that utilizes a SAM pathway.

Mazur et al. teach a comprehensive study to determine the levels of phytoestrogens and isoflavonoids found in 52 different food legumes (seeds), including soy and kudzu root. The six different isoflavonoids/phytoestrogens and coumestrol levels were measured and show that soybean provides a significant source of each (see the *Glycine* genus, four different soy products, p. 197, 1st four lines of Table 1). However, it also taught that kudzu root contains more formononetin, biochanin A, daidzein, coumestrol than the soy products, and genistein ranked second only behind soy whereas and secoisolariciresinol was the only one which was not significantly produced in kudzu (see p. 198). Nonetheless, this is clear evidence that kudzu root is a good alternative source of phytoestrogens/isoflavonoids to soy isoflavonoids/phytoestrogens.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the source of the isoflavonoids (e.g. soy) used in the composition to treat menopause as taught in Bagchi et al., and instead to use kudzu root isoflavonoids because Mazur et al. teach that kudzu root is a better source for four out of the seven phytoestrogens than soy. Furthermore, one skilled in the art would have reasonable expectation of success in doing so because both soy and

Art Unit: 1656

kudzu root contain the exact same phytoestrogen chemical compounds as shown in Figure 1, p. 195. Thus, administering a composition containing kudzu root isoflavonoids, an isoflavone synergist (resveratrol) and a methylating support compound (folic acid) as taught in Bagchi et al. would expected to manage a bodily process, e.g. menopause, which is known to use the SAM pathway.

Conclusion

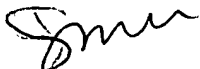
14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is 571-272-2924. The examiner can normally be reached on Monday to Friday, 7.00am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr or Jon Weber can be reached on 571-272-0931 or 571-272-0925, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

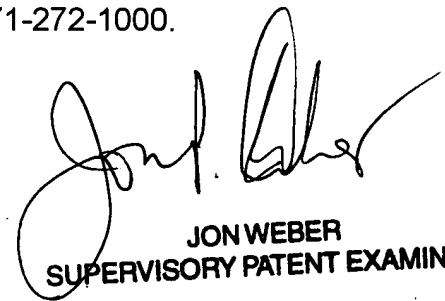
Art Unit: 1656

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SMN

20 November 2006



JON WEBER
SUPERVISORY PATENT EXAMINER